

GOVERNOR'S OFFICE OF CRIME PREVENTION, YOUTH, AND VICTIM SERVICES

Report of the Pilot Program for Preventing HIV Infection for Rape Victims

2020 Joint Chairmen's Report - FY 2021 Operating and Capital Budgets (Pages 33-34)

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December 1, 2020 2020 JCR (Pages 33-34)

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Introduction

The 2020 Joint Chairmen's Report - FY 2021 Operating and Capital Budgets (Pages 33-34) requires the Governor's Office of Crime Prevention, Youth, and Victim Services (Office) - previously known as the Governor's Office of Crime Control and Prevention¹ - to submit a report to the budget committees by December 1, 2020, as it relates to the care for post-exposure prophylaxis administered through the Pilot Program for Preventing Human Immunodeficiency Virus Infection for Rape Victims.² Specifically, and pursuant to the 2020 Joint Chairmen's Report - FY 2021 Operating and Capital Budgets (Pages 33-34), the report shall include the following:

- 1. The number of patients that qualified to receive post-exposure prophylaxis under the pilot program;
- 2. The number of patients that chose to receive post-exposure prophylaxis;
- 3. The total number requested for reimbursement by providers and the total amount reimbursed to providers for the post-exposure prophylaxis;
- 4. The number of requests for reimbursements submitted, granted, and denied, including the reasons for each request denied;
- 5. The cost of the post-exposure prophylaxis treatment and follow-up care provided under the pilot program;
- 6. The date the pilot program was fully implemented; and
- 7. Discussion of the process for treatment providers to apply for and receive reimbursement under this program.

In addition, the 2020 Joint Chairmen's Report - FY 2021 Operating and Capital Budgets (Pages 33-34), restricts the expenditure of funds until the Office submits the required report.³

Background

The Maryland Sexual Assault Reimbursement Unit (SARU) was established under Health-General § 15-127 and is regulated under the Code of Maryland Regulations (COMAR) 10.12.02, *Rape and Sexual Offenses – Physician and Hospital Charges*. The The SARU provides

³ Ibid.

¹ Maryland General Assembly. (2020). <u>Chapter 11, Acts of 2020</u>. In March 2020, the Governor's Office of Crime Control and Prevention was renamed the Governor's Office of Crime Prevention, Youth, and Victim Services.

² Department of Legislative Services. (2020). <u>2020 Joint Chairmen's Report: Report on the Fiscal 2021 State Operating Budget (SB 190) And the State Capital Budget (SB 191) And Related Recommendations</u>.

reimbursement for hospitals, physicians, and laboratories providing emergency medical treatment and evidence collection examinations for alleged victims of sexual assault.

Chapter 442 of the Acts of 2018 transferred the SARU from the Maryland Department of Health to the newly established Victim Services Unit (VSU) of the Governor's Office of Crime Prevention, Youth, and Victim Services (the Office), effective July 1, 2018. As a result of this transfer, the SARU now comprises one half of the Criminal Injuries Compensation Fund (CICF), while the Criminal Injuries Compensation Board (CICB) comprises the remaining half. This partnership promotes linkage of bill payment and reimbursement for all applicable services provided on behalf of crime victims.

Effective October 1, 2019, Chapter 431 of 2019 established the Pilot Program for Preventing Human Immunodeficiency Virus (HIV) Infection for Rape Victims (Pilot Program) to be administered by the VSU.⁴ Under this program, a victim of an alleged rape or sexual offense or a victim of alleged child sexual abuse would be provided with a full course of non-occupational post-exposure prophylaxis (nPEP) treatment and follow-up care for the prevention of HIV infection.

Following the 2020 legislative session, the 2020 Joint Chairmen's Report - FY 2021 Operating and Capital Budgets (Pages 33-34) directed the Office to submit a report to the budget committees on the **number of patients qualified to receive HIV therapy**, **the number of patients who chose to receive it**, and the **costs associated with the Pilot Program**. In accordance with the 2020 Joint Chairmen's Report - FY 2021 Operating and Capital Budgets (Pages 33-34), this Report of the Pilot Program for Preventing HIV Infection for Rape Victims reflects the requested information and outlines the process of receiving reimbursement through the program.

For an overview of nPEP therapy, cost estimates, and barriers to obtaining nPEP therapy, refer to the Maryland Department of Health's <u>2018 Joint Chairmen's Report on Prophylactic HIV</u> Therapy.

Sexual Assault Reimbursement Unit

The SARU was created to provide reimbursement for the physical examination, collection of evidence, and emergency treatment of individuals for injuries resulting from alleged rape, sexual assault, or child sexual abuse. The SARU aims to prevent individuals and their families from

⁴ Maryland General Assembly. (2019). <u>Chapter 431 of 2019 (Senate Bill 657)</u>, <u>Pilot Program - Alleged Rape, Sexual Offense</u>, or Child Sexual Abuse - HIV Postexposure Prophylaxis.

⁵ Department of Legislative Services. (2020). 2020 Joint Chairmen's Report: Report on the Fiscal 2021 State Operating Budget (SB 190) And the State Capital Budget (SB 191) And Related Recommendations.

re-victimization by easing the reimbursement process associated with medical-forensic claims processing. The SARU allows victims and their families to focus on the important task of healing. Reimbursements are made directly to physicians, hospitals, and laboratories on behalf of victims of rape, sexual assault, and child sexual abuse for medical treatment and evidence collection.

Through the SARU, the following services are covered:

- Emergency room treatment, in-hospital treatment, and follow-up medical testing obtained within 90 days of the initial examination for injuries sustained as a result of the alleged rape or sexual assault;
- Screening for pregnancy and sexually transmitted infections;
- Diagnostic tests directly associated with the assault;
- Laboratory tests necessary to establish and gather information and evidence of the crime;
- Toxicology screening;
- Postcoital medications;
- Prophylactic medications for sexually transmitted infections and tetanus;
- Pain and antiemetic medications; and
- Any medication directly related to the assault.

Pilot Program for Preventing HIV for Rape Victims

Implementation

Chapter 431 of 2019 established the Pilot Program and required the Office to administer the program, effective October 1, 2019.⁶ Pursuant to this Act, the physician, qualified healthcare provider, or hospital is entitled to be paid by CICF; however, the total amount paid may not exceed \$750,000 annually.⁷ The Act also requires the Office to submit a report to the Governor and the General Assembly by December 1, 2021, on the operation and results of the Pilot Program.⁸

Pursuant to this charge, the Office and core stakeholders created a statewide protocol to provide

⁶ Maryland General Assembly. (2019). <u>Chapter 431 of 2019 (Senate Bill 657)</u>, <u>Pilot Program - Alleged Rape, Sexual Offense</u>, or <u>Child Sexual Abuse - HIV Postexposure Prophylaxis</u>.

⁷ Department of Legislative Services. (2019). <u>Senate Bill 657 (2019)</u>, <u>Pilot Program - Alleged Rape</u>, <u>Sexual Offense</u>, <u>or Child Sexual Abuse - HIV Postexposure Prophylaxis (Fiscal and Policy Note Third Reader - Revised)</u>.

⁸ Maryland General Assembly. (2019). *Chapter 431 of 2019 (Senate Bill 657)*, *Pilot Program - Alleged Rape, Sexual Offense, or Child Sexual Abuse - HIV Postexposure Prophylaxis*. The report must include: (1) the number of patients that qualified to receive post-exposure prophylaxis under the Pilot Program; (2) the number of patients that chose to receive post-exposure prophylaxis; (3) the total amount reimbursed to providers for the post-exposure prophylaxis; and (4) the cost of the post-exposure prophylaxis treatment and follow-up care provided under the Pilot Program.

guidance on the implementation and operation of the Pilot Program, as well as instruction to ensure victims of sexual assault are served in the most efficient and effective manner. The statewide protocol also includes the <u>Centers for Disease Control and Prevention (CDC) Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV which will be used for the Pilot Program. The Office and core stakeholders finalized the statewide protocol, which has been approved, and will be available no later than December 1, 2020.</u>

The stakeholders involved in the development of the Pilot Program include the following:⁹

- Maryland Coalition Against Sexual Assault (MCASA)*
- Maryland Hospital Association (MHA)*
- Maryland Sexual Assault Evidence Kit Policy and Funding Committee (SAEK)*
- Maryland Department of Health*
- Maryland Board of Pharmacy
- Maryland SAFE Hospitals*
- Retail Pharmacies (CVS and Walgreens)
- Mail-Order Pharmacy Terrapin Pharmacy
- HIV Drug Manufacturer Gilead Sciences, Inc.
- South Carolina Department of Crime Victim Compensation
- Kentucky Crime Victims Compensation Fund Program
- The National Alliance of State & Territorial AIDS Directors (NASTAD)

Barriers & Efforts to Address Barriers

Prior to the enactment of Chapter 431 of 2019, which created the Pilot Program, the Office identified several implementation barriers, to include the following:

- 1. Availability of funding and the impact on the CICF via the SARU
- 2. Where the medication will be dispensed
- 3. Availability of medication to victims
- 4. Cost to facilities to stock medication
- 5. Training of medical providers and victim service providers
- 6. Most effective method of ensuring patient compliance and completion of the treatment process
- 7. Ensuring adequate follow-up care for victims
- 8. Follow-up care after six months for victims
- 9. Victim privacy concerns versus billing information needed to properly process claims

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⁹ It is important to note that the core stakeholders are denoted with an asterisk (*).

10. Appropriate data collection to measure effectiveness of the Pilot Program

To address these barriers, the Office has been involved in over 50 meetings with core stakeholders and other requisite parties to aid in the development of the protocol. Some of the efforts to eradicate barriers pertaining to the Pilot Program, include the following (as illustrated below and on the following page):

- Availability of funding and the impact on the CICF via the SARU. The VSU will continuously seek additional funding methods to aid the CICF in serving crime victims who have potentially been exposed to HIV as a result of a sexual assault.
- Where the medication will be dispensed. Ideally, the medication will be dispensed completely by a SAFE hospital. If a hospital is not able to provide the full course of medication, the medication is able to be provided through Terrapin Pharmacy while the victim is receiving services during the initial emergency room visit. If this does not occur, Terrapin Pharmacy is able to have the medication delivered to the victim via courier or mail order to the location of their choosing.
- Availability of the medication to victims. The Office and the core stakeholders involved in the development of the Pilot Program have been collaborating with Terrapin Pharmacy and have been reassured that the medication is able to be delivered to the address provided by the victim or via courier to an alternate address.
- Cost to facilities to stock medication. The cost of nPEP therapy ranges from \$350.00 \$4,500.00. This cost can be concentrated within one entity or spread out among several service providers depending upon a host of factors surrounding the victim. There is no way to calculate the cost of medication in advance due to a host of unknown variables and variances in each step of this process. Victims can receive this medication under a number of circumstances dependent upon the services available to them in their geographic region of the state. This includes receiving:
 - a. Full course of therapy provided at a SAFE or a non-SAFE hospital
 - b. Starter pack provided at a SAFE or a non-SAFE hospital
 - c. Remaining therapy provided at retail, independent, or designated mail order Pharmacy (Terrapin Pharmacy)
 - d. No medication provided at a hospital
 - e. Full course of therapy provided at a retail pharmacy
 - f. Full course of therapy provided at an independent pharmacy
 - g. Partial therapy provided at a retail pharmacy
 - h. Partial therapy provided at an independent pharmacy
 - i. Full course of therapy provided by a designated mail order company (Terrapin Pharmacy)
- Training of medical providers and victim service providers. The Office along with

core stakeholders, are awaiting approval of the statewide protocol to be utilized by medical providers and victim service providers. The protocol has been approved and will be ready for dissemination no later than December 1, 2020. It is important to note that an interim guidance and an abbreviated protocol were provided by the Office on January 17, 2020 and March 6, 2020, respectively, and disseminated by the Mayland Hospital Association and the Maryland Coalition Against Sexual Assault. These documents instructed medical providers and victim service providers on how to receive reimbursement for the treatment, medication, and follow-up care of victims of sexual assault.

- Most effective method of ensuring patient compliance and completion of the treatment process. The Office and core stakeholders have made every effort to eliminate barriers at every step of the process of victimization from the initial visit to follow-up care. The Office will continue to work with stakeholders to ensure that victims are referred for the appropriate case management or wrap-around services if they have contracted HIV as a result of a sexual assault.
- Ensuring adequate follow-up care for victims. The SARU will pay for all follow-up care resulting from the sexual assault for up to 180 days from the date of exposure.
- Follow-up care after six months for victims. After 180 days, the victim should be appropriately connected to service providers specialized in wrap-around HIV-related services to aid the victim on a long-term basis needed for the total recovery for the victim.
- Victim privacy concerns versus billing information needed to properly process claims. The Office, along with stakeholders, has created new SARU forms for utilization by medical providers to eliminate any privacy concerns. The forms have been approved and will be disseminated along with the official protocol no later than December 1, 2020. The Maryland Hospital Association, the Maryland Coalition Against Sexual Assault, as well as SAEK, will be instrumental in this process.
- Appropriate data collection to measure effectiveness of the Pilot Program. The Office has been collecting the required data for the Pilot Program since October 1, 2019.

The Office and core stakeholders also identified areas that require further guidance, to include the following:

- Further clarification for medical providers and victim service providers regarding various protocol areas, especially due to remote methods of dissemination of the protocol.
- Ensuring medication is stocked at hospitals, especially during the Coronavirus Disease 2019 (COVID-19) pandemic.
- Delivering medication to alternate addresses (including residential and businesses) especially during the COVID-19 pandemic.

- Funding at every aspect of the Pilot Program.
- Awareness of the Pilot Program.

Recommendation

The Office recommends the complete 28-day therapy be dispensed on-site at a medical facility at the initial visit, if possible. Patients will also receive instructions for follow-up care during the initial visit in order to provide clear information on follow-up services. It is recommended that victims seek follow-up care at the same location as their initial visit whenever possible.

The Office, via the SARU, has partnered with Terrapin Pharmacy to provide medication to patients where hospitals cannot provide the full 28-day therapy. Terrapin Pharmacy is able to provide medication to patients via mail delivery or courier. It is recommended that the facility be able to provide at least 3-7 days of therapy initially, and Terrapin Pharmacy will be able to provide the remainder of the therapy to ensure that the pharmacy will have adequate time to ensure that the victim receives the time-sensitive medication. The medication regimen must be started within 72 hours of the sexual assault. The facilities should be able to stock at least 3-7 days of medication due to weekends and holidays that might prevent mail-order or courier services from delivering the medication within the designated time frame.

The Office will reimburse for follow-up care when a victim is at risk for HIV contraction related to a sexual assault, following the Centers for Disease Control Guidelines at 4-6 weeks, and at three months and six months. Follow-up care after six months is recommended to occur at a local health department, HIV clinic, or a patient's primary care physician so that the victim can receive wrap-around services or case management services needed to appropriately address the victims' needs resulting from the sexual assault.

The Office will continue to collaborate quarterly with stakeholders to ensure that all aspects of the statewide protocol are serving victims of sexual assault in the most efficient and effective manner possible.

In instances where a facility cannot afford to stock the medication, or does not want to utilize Terrapin Pharmacy, medical facilities may utilize any of the following options:

- Refer a victim to a patient assistance program or co-pay assistance program
- Contact pharmaceutical manufacturers directly for the nPEP therapy drugs
- Send prescription to retail pharmacy on behalf of the victim
- Other methods facilities identify to provide medication

<u>Training Needs</u>

Given its complexity, the following professionals need to be trained in all aspects of the Pilot

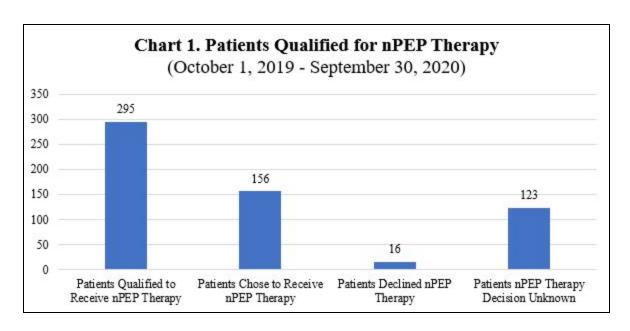
Program:

- Safe Nurses/Forensic Nurses
- Physician/Nurse Practitioners
- Emergency Department Staff
- Hospital Billing Staff
- Pharmacists (Technicians)
- Pharmacies and their Billing Offices
- Child Advocacy Centers (CAC)
- Victim Advocates (Comprehensive Programs and Hospital-Based)

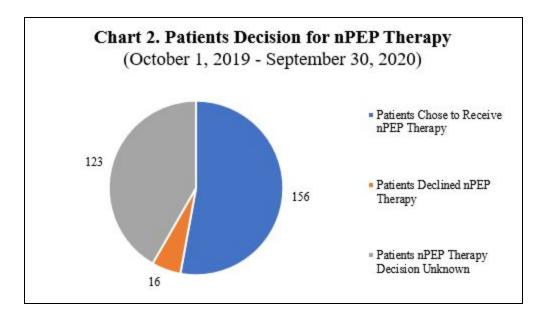
To assist with this need, the Office will host a webinar with MHA, MCASA, and Terrapin Pharmacy to train necessary professionals on the Pilot Program. Upon completion of the official statewide protocol rollout, the Office and core stakeholders will continue to collaborate to address any barriers that arise as the Pilot Program evolves. The Office recognizes that certain aspects of the program are subject to change and the Pilot Program must adapt accordingly in order to serve victims of sexual assault in the most efficient and effective manner.

Findings

Between October 1, 2019 and September 30, 2020, the SARU processed 295 claims for nPEP-related expenses - the term "claims" may be used interchangeably with "patients." Based on the nPEP claims, all patients were qualified to receive the nPEP therapy. As illustrated in Chart 1. Patients Qualified for nPEP Therapy, over 52% (n = 156) of the qualified patients chose to receive nPEP therapy. Of the 156 patients that chose to receive nPEP therapy, 75 claims were submitted and billed to the SARU for reimbursement, and 81 were submitted to the SARU yet covered by an alternate method. The 75 claims included reimbursement of the full course of medication (28-days), or a starter pack ranging from 1-7 days of medication; however, it was often not possible to determine the amount provided to a patient based on the documentation received by the SARU. The 81 claims identified patients who chose to receive nPEP therapy through an alternative method (e.g., a retail pharmacy, co-pay assistance program, etc.). Even though the 81 claims were submitted to the SARU, and used for documentation of the Pilot Program, the nPEP medication was not billed to the SARU. Based on the narrative information that was provided with each claim, the SARU was able to determine that the 81 claims had nPEP therapy covered by an alternate method. In the future, the new nPEP form will clearly provide this information to the SARU, which will be used in place of the narrative.

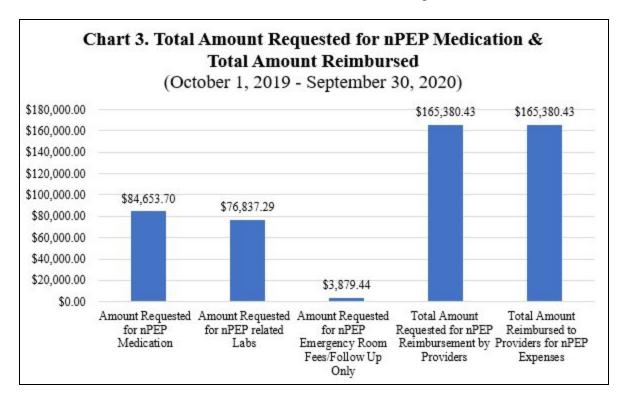


As illustrated in **Chart 2. Patients Decision for nPEP Therapy**, there were 16 patients that declined nPEP, and 123 patients where it was unknown if they chose to receive nPEP, as it was not billed to the SARU or stated within the claim. This means that the number of patients declining nPEP or receiving nPEP through an alternate method could be higher due to the unknown nature of nPEP usage of 123 claims.



Between October 1, 2019 and September 30, 2020, there were no claims that were processed as ineligible or denied. The total number of requests for reimbursement was 295. As illustrated in **Chart 3. Total Amount Requested for nPEP Medication & Total Amount Reimbursed**, the cost of nPEP therapy was \$84,653.70, and the cost for nPEP related labs was \$76,837.29. The

total amount reimbursed to providers for nPEP related expenses was \$165,380.43. The SARU received 277 claims for an initial visit, and 18 claims for follow-up visits.



Reasons for non-payment and ineligibility include the following: (1) if nPEP therapy was provided outside of the 72-hour time frame, (2) and/or if the SARU reached the \$750,000 annual threshold for nPEP related expenses.

It is important to note that in any instance in which a victim is unable to receive nPEP screening, medication, or follow-up care, the Office will collaborate with any medical facility, pharmacy, pharmaceutical company, or other related entity to ensure that the victim receives the recommended care. All inquiries should be sent to saru.claims@maryland.gov.

Conclusion

The Office will continue to work with stakeholders to coordinate the official announcement of the statewide protocol, and to address the identified recommendation and training needs to ensure victims of sexual assault are served in the most efficient and effective manner possible.